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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,529	12/30/2003	Yuegang Zhang	070702006000	8848
7590 01/18/2007 Raj S. Dave Morrison & Foerster LLP 1650 Tysons Blvd., Suite 300 McLean, VA 22102			EXAMINER SINES, BRIAN J	
			ART UNIT 1743	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/749,529

Applicant(s)

ZHANG ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-30 is/are pending in the application.
- 4a) Of the above claim(s) 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Election/Restrictions***

Applicant's election without traverse of group I comprising claims 1 and 3 – 24 in the reply filed on 10/30/2006 is acknowledged.

Claims 27 – 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b):

1. Claims 1 and 10 – 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 32 and 36 of copending Application No. 11/317,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because they appear to be directed to the same apparatus. Furthermore, the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
2. Claims 1, 3, 4 and 10 – 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 32 and 36 of copending Application No. 11/317,405. Although the conflicting claims are not identical, they are not patentably distinct from each other because they appear to be directed to the same device. Furthermore, the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

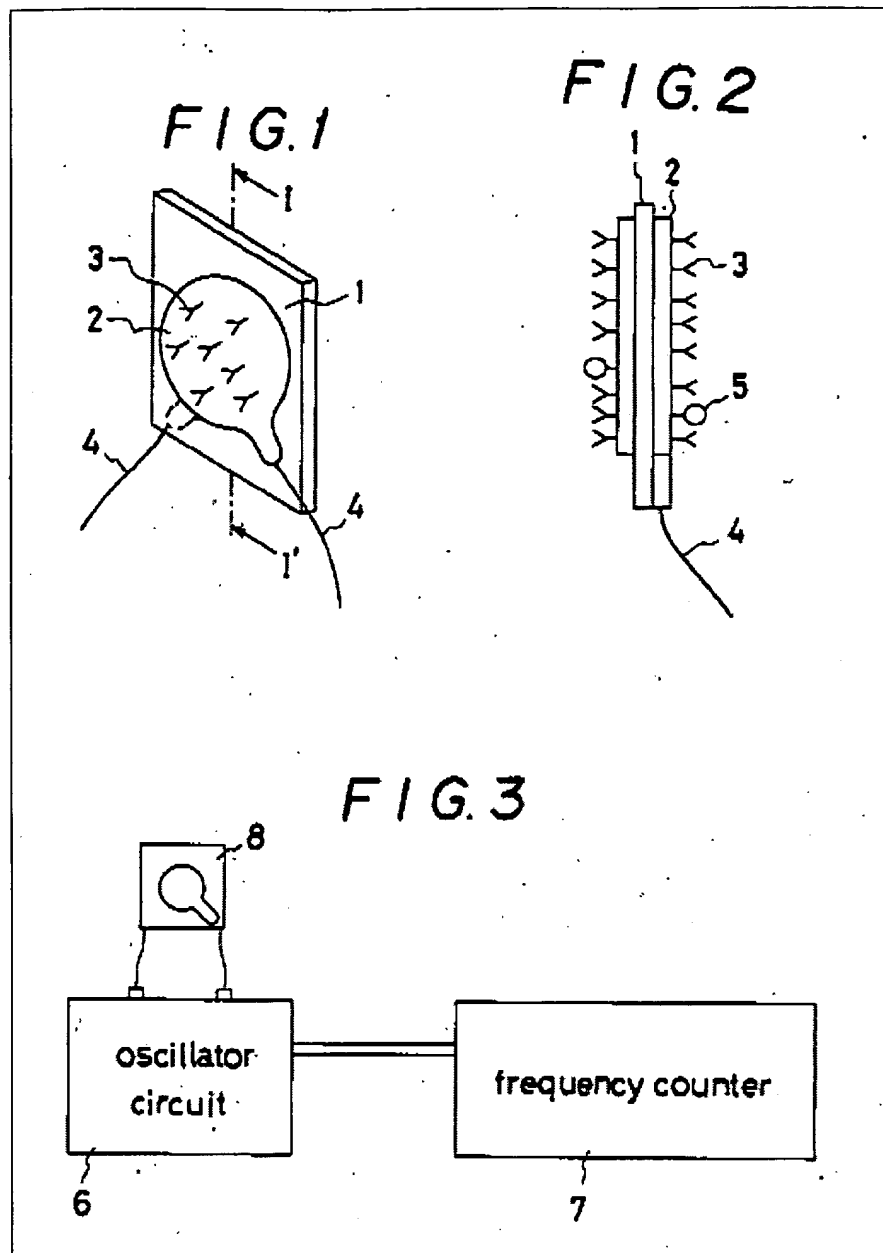
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 – 14 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Karube et al. (U.S Pat. No. 4,789,804) (hereinafter “Karube”).

Regarding claims 1 and 10 – 13, Karube teaches a biosensor comprising: a resonator comprising a layer of piezoelectric material 1 that is sandwiched between a pair of electrodes 2, wherein the electrodes 2 have a functionalized surface (e.g., a surface functionalized with immobilized antibodies 3 that bind with target molecules); and associated control and measurement circuitry (6 & 7) (see col. 's 3 & 4; figures 1 – 3). As shown in figure 14, the resonator (e.g., piezoelectric crystal 141) is positioned with edges of the resonator on a substrate or support structure (e.g., cell 144) (see col. 9, lines 30 – 47).



Regarding claims 5 – 9, these claims are considered statements of intended use regarding how the control circuitry is used to operate the claimed device. The disclosed measurement and control circuitry is capable of performing in the manner claimed. If the prior art structure is capable of performing the intended use, then it meets the claim. Apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. The manner of operating an apparatus does not differentiate an

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apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim (see MPEP § 2114).

Regarding claim 14, Karube anticipates the incorporation of an organic membrane. Karube teaches the use of an organic membrane film, wherein the concentration measurement is determined by measuring a change in the membrane potential (see, e.g., col. 1, lines 19 – 31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karube in view of Bastiaans (U.S. Pat. No. 4,735,906).

Regarding claim 4, Karube does not specifically teach the further incorporation of a second piezoelectric resonator and an additional pair of electrodes having a non-functionalized surface coupled to the second piezoelectric resonator, wherein the control circuitry is configured to apply the excitation signal to the additional pair of electrodes

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and to determine a frequency response for the second piezoelectric resonator. This second piezoelectric resonator would effectively function as a control or reference resonator for the detection device.

However, the use of non-functionalized reference sensors that are not specifically reactive to the target analyte molecules so as to compensate sensor detection measurements for non-specific effects, i.e., effects due to non-specific binding, temperature variation, etc., as shown by Bastiaans, is well known in the art (see, e.g., Abstract; col. 2, line 2 – col. 3, line 13; col. 4, lines 55 – 63; col.5, lines 38 – 55) (see MPEP § 2144.03). Baastians teaches a surface acoustic wave sensor system utilizing piezoelectric crystals and comprising a measurement sensor 10 comprising electrodes 14 & 16 and a reference sensor 11 comprising a similar set of electrodes (see col. 3, line 25 – col. 5, line 37; figure 1). Consequently, as indicated by Baastians, a person of ordinary skill in the art would accordingly have recognized the suitability of incorporating the use of a reference sensor with the disclosed sensing device (see MPEP § 2144.07).

Therefore, it would have been obvious to a person of ordinary skill in the art to provide for the further incorporation of a secondary piezoelectric resonator and an additional pair of electrodes having a non-functionalized surface coupled to the second piezoelectric resonator, wherein the control circuitry is configured to apply the excitation signal to the additional pair of electrodes and to determine a frequency response for the second piezoelectric resonator. This second piezoelectric resonator would effectively function as a control or reference resonator for the detection device.

2. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karube and Bastiaans in view of Yamada et al. (U.S. Pat. No. 6,842,088 B2) (hereinafter “Yamada”).

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Regarding claim 4, the cited prior art does not specifically teach the use of piezoelectric resonators comprising film bulk acoustic resonators ("FBAR's").

However, Yamada teaches the use of film bulk acoustic resonator's as sensing devices (see, e.g., col. 1, lines 10 – 22). Consequently, as indicated by Yamada, a person of ordinary skill in the art would accordingly have recognized the suitability of using a film bulk acoustic resonator device for sensing (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a film bulk acoustic resonator as claimed with the disclosed sensing device.

3. Claims 14 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karube.

Regarding claims 14 and 15, Karube teaches the incorporation of an organic membrane. Karube teaches the use of an organic membrane film, wherein the concentration measurement is determined by measuring a change in the membrane potential (see, e.g., col. 1, lines 19 – 31). Hence, as indicated by Karube, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of incorporating an organic membrane as claimed with the disclosed sensing device for facilitating effective sensor functionalization and derivatization with immobilized antibodies (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an organic membrane as claimed with the disclosed sensing device.

Regarding claims 16 – 20, these claims recite various functionalization or immobilization chemistries that are well known in the art (see MPEP § 2144.03). Thus, a person of ordinary skill in the art would accordingly have had a reasonable expectation

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for success in using these immobilization and derivatization chemistries to facilitate sensor functionaliation (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of these functionalization chemistries for facilitating the effective immobilization of sensing ligands, such as antibodies.

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karube in view of Lipskier (U.S. Pat. No. 5,910,286 A).

Regarding claim 22, Karube does not specifically teach that a substrate or support structure for the resonator comprises a non-metallic inorganic film, such as a surface comprising silicon. However, as evidenced by Lipskier, the use of substrate support structures comprising silicon for piezoelectric-based sensors is well known in the art (see, e.g., col. 5, lines 14 – 44; figure 3) (see MPEP § 2144.03). Consequently, as shown by Lipskier, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a silicon substrate surface as claimed with the disclosed apparatus. The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a silicon substrate surface as claimed with the disclosed apparatus to facilitate effective operation.

5. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karube in view of Fendler (U.S. Pat. Appl. No. 2006/0160144 A1).

Regarding claims 23 and 24, Karube does not specifically teach the incorporation of a functionalized surface comprising a self-assembling biomolecular layer comprising a

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lipid layer. However, Fendler teaches a sensor electrode arrangement comprising a functionalized surface comprising a self-assembling biomolecular layer comprising a lipid layer (see, e.g., paragraph 44). Consequently, as shown by Fendler, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of incorporating such a functionalized layer configuration with a sensor electrode for facilitating effective sensor measurements (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a functionalized electrode surface comprising a self-assembling biomolecular layer comprising a lipid layer.

Response to Arguments

Applicant's arguments with respect to the amended claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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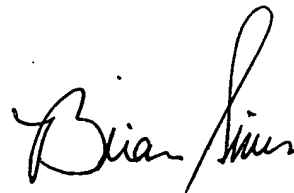
advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines
Primary Examiner
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A handwritten signature in black ink, appearing to read "Brian Sines", is located below the typed name and title.